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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/522,525

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David Dakin Iorwerth Wright

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12/14/2009

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EXAMINER

BROWN, COURTNEY A

ART UNIT

PAPER NUMBER

1616

MAIL DATE

DELIVERY MODE

12/14/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/522,525	Applicant(s) WRIGHT ET AL.	
	Examiner COURTNEY BROWN	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,5,8,9,12,16,18-20,25,27-29,31,64,87 and 88 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,5,8,9,12,16,18-20,25,27-29,31,64, and 87-88 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/15/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgement of Receipt/Status of Claims

This Office Action is in response to the amendment filed July 15, 2009. Claims 1,4,5,8,9,12,16,18-20,25,27-29,31,64 and 87-88 are pending in the application. Claims 2-3,6-7,10-11,13-15,17,21-24,26,30,32-63 and 65-86 have been cancelled. 1,4,5,8,9,12,16,18-20,25,27-29,31,64, and 87-88 are being examined for patentability.

Rejections not reiterated from the previous Office Action are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Information Disclosure Statement

The Information Disclosure Statements (IDS) submitted on September 24, 2009 has been considered by the examiner.

The obviousness-type double patenting rejection of claims **1,16,19,25 and 28** over claims **1, 15, 16** and **37** of copending Application No. 10/522,527 in view of Osman et al. (US Patent 6,572,873) is **maintained**.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims **1, 16, 19, 25 and 28** are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims **1, 15, 16** and **37** of copending Application No. 10/522,527 in view of Osman et al. (US Patent 6,572,873). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed subject matter embraces or is embraced co-pending application 10/522,527.

The copending application recites the same composition: a foam comprising a liquid phase and a gas phase wherein the liquid phase comprises at least one sclerosing agent (polidocanol or tetradecyl sulphate) and at least one viscosity enhancing agent (glycerol or PVP), the liquid phase having a viscosity between ranging

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from 2cP to 5cP; and the gas phase comprises CO₂ wherein the foam has a density less than 0.25 g/ml and half life of greater than 90 seconds. The difference between the invention of the instant application and that of copending application 10/522,527 is that the instant invention has a gas phase of at least 90% CO₂ as opposed to having from 0.001-0.8% nitrogen and at least one other gas chosen from O₂ and CO₂. However, Osman et al. teach a microfoam wherein the gas used is a mixture of carbon dioxide and other physiological gases, particularly containing 3% or more carbon dioxide, more preferably from 10 to 90% carbon dioxide, most preferably 30 to 50% carbon dioxide and other components, preferably oxygen with a minor proportion only of nitrogen being preferred (column 5, lines 59-65). From this extensive overlap of subject matter, one of ordinary skill in the art would recognize that the same product is taught in copending application 10/522,527.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The obviousness-type double patenting rejection of claims **1 and 19** are p over claims **1, 9, 10, 13** and **14** of copending Application No. 10/890,267 in view of Osman et al. (US 6,572,873) is maintained.

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Claims **1 and 19** are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims **1, 9, 10, 13** and **14** of copending Application No. 10/890,267 in view of Osman et al. (US 6,572,873). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed subject matter embraces or is embraced by copending application 10/890,267.

The copending application recites the same composition: a foam comprising a liquid phase and a gas phase wherein the liquid phase comprises at least one sclerosing agent (polidocanol or tetradecyl sulphate) wherein the gas phase comprises at least 90% CO₂; and wherein the foam has a density less than 0.25 g/ml and half life of greater than 90 seconds. The difference between the invention of the instant applicant and copending Application 10/890,267 is that the instant invention uses a viscosity agent. However, Osman et al. teach the use of a viscosity agent, glycerol, in a microfoam composition that comprises polidocanol and CO₂ (column 14, lines 5-12). From this extensive overlap of subject matter, one of ordinary skill in the art would recognize that the same product is taught in copending application 10/890,267.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The obviousness-type double patenting rejection of claims **1, 16 and 19** are over claims **1, 7, 9 and 15-17** of copending Application No. 11/128,265 in view of Osman et al. (US Patent 6,572,873). **is maintained.**

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Claims **1, 16 and 19** are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims **1, 7, 9 and 15-17** of copending Application No. 11/128,265 in view of Osman et al. (US Patent 6,572,873). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed subject matter embraces or is embraced co-pending application 11/128,265.

The copending application recites the same composition: a foam comprising a liquid phase and a gas phase wherein the liquid phase comprises at least one sclerosing agent (polidocanol or tetradecyl sulphate) and at least one viscosity enhancing agent (glycerol or PVP), the liquid phase having a viscosity between ranging from 2cP to 5cP; and the gas phase comprises CO₂; and wherein the foam has a density less than 0.25 g/ml and half life of greater than 90 seconds. The difference between the invention of the instant application and of copending application 11/128,265 is that the instant invention has a gas phase of at least 90% CO₂ as opposed to having from 0.001-.8% nitrogen gas, xenon gas in an amount greater than 5% and at least one other gas chosen from O₂ and CO₂. However, Osman et al. teach a microfoam composition wherein the gas used is a mixture of carbon dioxide and other physiological gases, particularly containing 3% or more carbon dioxide, more preferably from 10 to 90% carbon dioxide, most preferably 30 to 50% carbon dioxide and other components, preferably oxygen with a minor proportion only of nitrogen being preferred (column 5, lines 59-65). It would have been obvious to one of ordinary skill in the art to use xenon gas in an amount greater than 5% because the solubility of Xenon at STP is

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7.9 and would therefore disperse in blood like oxygen and carbon dioxide (see column 2, Table 1, lines 40-49 of Osman et al.) . From this extensive overlap of subject matter, one of ordinary skill in the art would recognize that the same product is taught in copending application 11/128,265.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The obviousness-type double patenting rejection of claims **1, 16 and 19** over claims **1, 2, 7, 8, 16 and 17** of copending Application No. 11/914,190 in view of Osman et al. (US Patent 6,572,873) **is maintained**.

Claims **1, 16 and 19** are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims **1, 2, 7, 8, 16 and 17** of copending Application No. 11/914,190 in view of Osman et al. (US Patent 6,572,873). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed subject matter embraces or is embraced co-pending application 11/914,190.

The copending application recites the same composition: a foam comprising a liquid phase and a gas phase wherein the liquid phase comprises at least one sclerosing agent (polidocanol or tetradecyl sulphate) and at least one viscosity enhancing agent (glycerol or PVP) ;the gas phase comprises CO₂ wherein the foam has a density less than 0.25 g/ml and half life of greater than 90 seconds. The difference between the invention of the instant application and of copending application

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11/914,190 is that the instant invention has a gas phase of at least 90% CO₂ as opposed to having from 0.001-.8% nitrogen gas, xenon gas in an amount greater than 5% and at least one other gas chosen from O₂ and CO₂. However, Osman et al. teach a microfoam wherein the gas used is a mixture of carbon dioxide and other physiological gases, particularly containing 3% or more carbon dioxide, more preferably from 10 to 90% carbon dioxide, most preferably 30 to 50% carbon dioxide and other components, preferably oxygen with a minor proportion only of nitrogen being preferred (column 5, lines 59-65). It would be obvious to one of ordinary skill in the art to use xenon gas in an amount greater than 5% the solubility of Xenon at STP is 7.9 and would therefore disperse in blood just like nitrogen, carbon dioxide, and oxygen (see column 2, Table 1, lines 40-49 of Osman et al.). From this extensive overlap of subject matter, one of ordinary skill in the art would recognize that the same product is taught in copending application 11/914,190.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The obviousness-type double patenting rejection of claims **1, 16, 19, 25 and 28** over claims **61, 64** and **68-70** of copending Application No. 11/225,860 in view of Osman et al. (US Patent 6,572,873) is maintained.

Claims **1, 16, 19, 25 and 28** are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims **61,**

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64 and **68-70** of copending Application No. 11/225,860 in view of Osman et al. (US Patent 6,572,873). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed subject matter embraces or is embraced co-pending application 11/225,860.

The copending application recites the same composition; a foam comprising a liquid phase and a gas phase wherein the liquid phase comprises at least one sclerosing agent (polidocanol or tetradecyl sulphate) wherein the gas phase comprises CO₂; and wherein the foam has a density less than 0.25 g/ml and half life of greater than 90 seconds. The difference between the invention of the instant applicant and copending Application 11/225,860 is that the instant invention uses a viscosity agent. However, Osman et al. teach the use of a viscosity agent, glycerol, in a microfoam composition (column 14, lines 5-12) that comprises polidocanol and CO₂. From this extensive overlap of subject matter, one of ordinary skill in the art would recognize that the same product is taught in copending application 11/225,860.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Examiner's Response to Applicant's Remarks

Applicant's arguments, filed on July 15, 2009, with respect to the obviousness-type double patenting rejection(s) of claims 1, 16, 19, 25 and 28 have been fully considered but they are not persuasive. Applicant argues that the obviousness

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determination under 35 U.S.C. § 103 is modified in one important way and that unlike a § 103 obvious determination in which the entire prior art reference teaches is relevant, only the claims and not the disclosure of the patent may be used to formulate a double patenting rejection. However, the Examiner disagrees with Applicant's argument.

The analysis employed in an obviousness-type double patenting rejection parallels the guidelines for analysis of a 35 U.S.C. 103 obviousness determination. In *re Braat*, 937 F.2d 589, 19 USPQ2d 1289 (Fed. Cir. 1991); In *re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Since the analysis employed in an obviousness-type double patenting determination parallels the guidelines for a 35 U.S.C. 103(a) rejection, the factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103 are employed when making an obvious-type double patenting analysis. See M.P.E.P. § 804.

Applicant also argues that none of the claims of the co-pending applications teach the claimed viscosity range. The Examiner agrees with Applicant's arguments because the teaching of Osman et al. was joined to show that the use of a viscosity agent, glycerol, in a microfoam composition (column 14, lines 5-12 of Osman et al.) was known at the time of the instant invention. Thus, the obviousness-type double patenting rejection(s) of claims 1, 16, 19, 25 and 28 are maintained.

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The rejection of claims 1,4,5,8,9,12,16,18-20,25,27-29,31,64, and 87-88 under 35 U.S.C. 103(a) over Osman et al. (US Patent 6,572,873 B1) **is maintained**.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 4, 5, 8, 9, 12, 16, 18-20, 25, 27-29, 31, 64, and 87-88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Osman et al. (US Patent 6,572,873 B1).

Applicant's Invention

Applicant claims a foam comprising a liquid phase and a gas phase wherein the liquid phase comprises at least one sclerosing agent and at least one viscosity enhancing agent, the liquid phase having a viscosity between ranging from 2cP to 5cP; and the gas phase comprises at least 90% CO₂; and wherein the foam has a density less than 0.25 g/ml and half life of greater than 90 seconds.

***Determination of the scope and the content of the prior art
(MPEP 2141.01)***

Osman et al. teach a microfoam comprising a physiologically acceptable gas that is dispersible in the blood and an aqueous sclerosant liquid wherein the sclerosant is aqueous polidocanol, the concentration of polidocanol being from 0.5 to 4% vol/vol in the liquid (see column 5, lines 59 to 65 and column 6, lines 13-18). Foams taught

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contain glycerol, which is a viscosity enhancing agent (column 6, lines 36-40), which inherently produces a viscosity of the liquid phase between 2 cP and 5 cP since it is the same viscosity agent that Applicant uses. At worst, one skilled may need to vary the amount of glycerol but the problem is discussed in Osman et al. so it would be obvious to vary. Addition of the glycerol to the composition imparts a longer half-life to the resulting foam (column 13, lines 15-16). The foam density preferred by Osman et al. is between 0.07 g/ml and 0.19 g/ml (less than 0.25 g/ml) with a half life of at least 2 minutes (greater than 90 sec) (see column 5, lines 5-6). The foam gas may be CO₂ and can range from 10 to 90% (see column 5, lines 59-65). Osman et al. provide a method for producing said microfoam characterized in that it comprises passing a mixture of a physiologically acceptable blood dispersible gas and an aqueous sclerosant liquid through one or more passages having at least one cross-sectional dimension or from 0.1 to 30 μ m (column 4, line 64 bridging to column 5, lines 1-6). Preferably the microfoam is such that 50% or more by number of its gas bubbles of 25 μ m diameter and over are no more than 200 μ m diameter and the gas/liquid ratio in the mix is controlled such that the density of the microfoam is 0.09 g/mL to 0.16 g/mL, more preferably 0.11 g/mL to 0.14 g/mL (column 5, lines 9-11). Advantageously and preferably the method provides foam characterized in that at least 50% by number of its gas bubbles of 25 μ m diameter and over are of no more than 130-150 μ m diameter, more preferably at least 95% of these gas bubbles by number are of no more than 250-280 μ m diameter (column 5, lines 25-33). When a canister device is used, it is sized such the amount of gas under pressure in such canisters should be sufficient to produce

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enough foam to fill, at least one varicosed human saphenous vein (column 11, lines 27-33).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

The difference between the instant invention and Osman et al. is that Osman et al. does not exemplify a composition in which the gas phase comprises at least 90% CO₂.

Finding of prima facie obviousness

Rationale and Motivation (MPEP 2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the teaching of the cited reference to arrive at a foam comprising a liquid phase and a gas phase wherein the liquid phase comprises at least one sclerosing agent and at least one viscosity enhancing agent, the liquid phase having a viscosity between ranging from 2cP to 5cP; and the gas phase comprises at least 90% CO₂. Osman et al., on column 5, lines 61-62, teach a preference for a CO₂ content of 10 to 90%. The instantly claimed invention would have therefore been obvious to one

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of ordinary skill in the art at the time of the invention because Osman et al. teaches that a CO₂ content of 90% may be used.

All the claimed elements were known in the prior art and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions, and the combination would have yielded predictable results to one of ordinary skill in the art at the time of the invention.

Therefore, the claimed invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made because every element of the invention has been fairly suggested by the cited reference.

Response to Arguments

Applicant's arguments filed on November 23, 2008 have been fully considered but they are not persuasive. Applicant argues that, as discussed in the interview on December 19, 2008, claims 1, 4, 5, 8, 9, 12, 16, 18-20, 25, 27-29, 31, 64, and 87-88 are not obvious under 35 U.S.C. § 103 in view of Osman et al. WO 00/72821 (International Application Published Under the PCT, Published 12/07/2000). Applicant argues that the Osman et al. is silent as to the viscosity of the liquid phase of the foam, while the present invention requires "at least one viscosity enhancing agent, the liquid phase having a viscosity ranging from 2cP to 5 cP," as claimed in claim 1. Osman does mention stabilizing agents, including glycerol, as optional components. However, Osman also cautions that while addition of glycerol "imparts a longer half-life to the

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resultant foam, glycerol also produces a tendency for the meshes to block up." See Osman, col. 13, 11 and 15-19. However, the Examiner disagrees because Osman et al., as Applicant pointed out, do teach foams containing glycerol, which is a viscosity enhancing agent (column 6, lines 36-40), which inherently produces a viscosity of the liquid phase between 2 cP and 5 cP since it is the same viscosity agent that Applicant uses. The Examiner points to the fact that a composition that consists of the same components (i.e. glycerol) will possess the same properties and therefore lead to identical, desired results. Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical component, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Applicant further argues that the claimed invention is not obvious in view of Osman because there is no suggestion or motivation in the prior art to combine the claimed limitations. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Osman et al. teach foams containing glycerol, which is a viscosity enhancing agent (column 6, lines 36-40), which

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inherently produces a viscosity of the liquid phase between 2 cP and 5 cP since it is the same viscosity agent that Applicant uses. At worst, one skilled may need to vary the amount of glycerol but the problem is discussed in Osman et al. so it would be obvious to vary. Addition of the glycerol to the composition imparts a longer half –life to the resulting foam (column 13, lines 15-16). The foam density preferred by Osman et al. is between 0.07 g/ml and 0.19 g/ml (less than 0.25 g/ml) with a half life of at least 2 minutes (greater than 90 sec) (see column 5, lines 5-6). The foam gas may be CO₂ and can range from 10 to 90% (see column 5, lines 59-65).

Applicant argues that the addition of glycerol does not inherently produce a viscosity ranging from 2cP and 5cP, as recited in claim 1. Moreover, Applicant argues that the modification of Osman to produce the claimed foam with a viscosity ranging from 2cP and 5cP is not the result of routine optimization or experimentation for at least the reason that Osman provides no guidance as to what one of skill in the art would optimize. However, the Examiner disagrees with Applicant's argument because the U.S. Patent Office is not equipped with analytical instruments to test prior art compositions for the infinite number of ways that a subsequent applicant may present previously unmeasured characteristics. When as here, the prior art appears to contain the exact same ingredients and applicant's own disclosure supports the suitability of the prior art composition as the inventive composition component, the burden is properly shifted to applicant to show otherwise.

Applicant argues that there are simply too many potential parameters to vary given the general guidance and broad disclosure of Osman. Specifically, Applicant

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argues that there are six claim elements (variables) that are interrelated: amount of sclerosing agent, amount of viscosity enhancing agent, density, viscosity, half-life, and composition of the gas phase. Applicant argues that only using impermissible hindsight would one of skill in the art know how to optimize so many variables. However, the Examiner disagrees with Applicant's arguments. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

In light of the forgoing discussion, the Examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

The claims remain rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR Only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the

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examiner should be directed to Examiner Courtney Brown, whose telephone number is 571-270-3284. The examiner can normally be reached on Monday-Friday from 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Courtney A. Brown
Patent Examiner
Technology Center 1600
Group Art Unit 1616

/Mina Haghighatian/
Primary Examiner, Art Unit 1616